

DETAILED ACTION

Status of the Application

1. This is a divisional application, filed 7/30/01, of parent case 09/203,679, filed 12/01/98.
2. Claims 22-29 are pending.
3. The preliminary amendment dated 7/30/01 has been entered.

Specification

4. The specification is objected to because of the following informalities: The margins in the specification are too small and the bottom margin is so small as to possibly eliminate the last line of text. A substitute specification is required.
5. The status of all cited US patent applications must be included and updated as applicable.
6. Table I, pages 12 and 13 need to be resubmitted because the columns are not aligned and the recipes are unclear.
7. Correction is required.

Claim Rejections - 35 USC § 112 second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,965	07/30/2001	Herbert Martin Wilson	N1205-014	1608

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,965

Applicant(s)

WILSON ET AL.

Examiner

Georgia Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

9. Claims 22-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 22,

- "transforming lines of corn" is unclear. Tissue or cells can be transformed; lines are multiple individuals and cannot, as such, be transformed.
- In (a): The term "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. This does not appear to be applicant's intention. It is suggested that "gene" be amended to "a polynucleotide encoding a protein of interest".
- In (b), "said" needs to be inserted before "co-cultivation"; "said sugar being" needs to be inserted after "sugar" for clarity.
- The Office interprets concentration terms like "mg/L and g/L" to be the final concentration in the medium.
- In (c), both "antibiotic" and "selective agent" are recited and it is unclear how these differ, as antibiotics are a selective agent.
- In (c), "resulting tissue" lacks antecedence; "an" antibiotic should be "said" antibiotic, for proper antecedence unless Applicant is referring to an additional antibiotic.
- In (d), "resulting tissue" lacks antecedence; "a" selective agent should be "said" selective agent, for proper antecedence.

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- In (e), "with growing type II callus" is unclear; is "growing" the criterion for selection or is it an inherent property of the recited type II callus? Does "with" mean "having" or "and"?
- In (e) "water tower embryo structures" is unclear. Lacking an adequate description, this term should be eliminated.

Claim 22 is an incomplete claim since the desired product of the method is produced in the final step.

In claim 24, "Agrobacterium is selected" implies some selective agent being used, which is not the case here. Replacing "selected" with "taken" is suggested.

Claim 27 is recited to depend on claim 25. However the Office interprets claim 27 to depend on claim 26; otherwise "said heat shock" would lack antecedence.

In claim 28, "said" should be inserted before "antibiotic" for proper antecedence.

Claim 29 depends on a cancelled claim. To expedite prosecution, the Office interprets claim 29 as depending on claim 22.

10. Clarification and/or correction is required.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Patentability shall not be negated by the manner in which the invention was made.

12. Claims 22, 23 and 29 are rejected 35 U.S.C. 103(a) as being unpatentable over Hansen, G. (US # 6,162,965) filed June 2, 1997, issued December 19, 2000, in view of Bhojwani, SS et al (Developments in Crop Science, vol 5, pp 24-41, 1983. Hansen teaches

- a method for transforming corn (9th column, lines 6-16),
- comprising the steps of cocultivating an immature embryo (8th column, lines 2-25; 9th column, lines 6-9)
- with Agrobacterium capable of transferring at least one gene (8th column, lines 57-63) to tissue to produced an infected embryo,
- culturing the infected embryo after cocultivation on a medium comprising an antibiotic (9th column, lines 14-16), and glucose (13th column, lines 4-7),
- culturing resulting tissue on medium comprising and antibiotic and a selective agent (16th column, lines 5-9).
- Hansen further teaches Type II callus (5th column, lines 15, 16), and regenerating plants from embryos (16th column, lines 10-16).

Hansen does not teach a plant growth medium comprising a monosaccharide sugar at 5-30 g/L, an antibiotic at 15-75 mg/L, and cocultivating at 19 C temperature.

Bhojwani states that monocots grow best on monosaccharides (pg 31, 2nd paragraph), and teaches plant growth media comprising the monosaccharide glucose at 20-50 g/L, as well as maltose and lactose (pg 31, 2nd paragraph). Therefore, one of skill

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in the art would have been motivated to substitute the disaccharide of Hansen with the monosaccharide of Bhojwani, for the purpose of growth enhancement for monocots such as corn, with a reasonable expectation of success.

It is unclear what constitutes "two passages" as set forth in the 112-second rejection supra. However culturing for two passages until callus formation would have been obvious in view of prior art teachings.

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

13. Claims 22, 23, 29 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen, G. (US # 6,162,965) filed June 2, 1997, issued December 19, 2000, Bhojwani, SS et al (Developments in Crop Science, vol 5, pp 24-41, 1983), as applied to claims 22,23 and 29, above, and further in view of Holton (US 5,948,955; issued September 7, 1999, PCT pub date Dec 8, 1994).

The combination of Hansen and Bhojwani does not teach one to two days of growth for Agrobacterium after rescue from frozen glycerol stocks prior to plant transformation. Holton teaches using Agrobacterium one day after rescue from frozen glycerol stocks (column 11, lines 27-35), prior to cocultivation. Accordingly, using Agrobacterium 1-2 days after rescuing from frozen glycerol stick is standard transformation procedure well within the means of one of ordinary skill, without any surprising or unexpected results. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

One of ordinary skill in the art would have been motivated to use *Agrobacterium* one day after rescue from frozen glycerol stocks because this would shorten the time needed for the overall process.

14. Claims 22, 23, 29 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen, G. (US # 6,162,965) filed June 2, 1997, issued December 19, 2000, Bhojwani, SS et al (Developments in Crop Science, vol 5, pp 24-41, 1983), applied to claims 22,23 and 29, above, and Applicant's admitted prior art. The teachings of Hansen and Bhojwani have been discussed supra.

The combination of Hansen and Bhojwani do not teach a cocultivation temperature of about 19 degrees C. However, Applicants admitted prior art (specification, page 15, 1st paragraph) shows that cocultivating at 19 degrees C temperature results in increased transformation. One skilled in the art would have been motivated, at the time of the invention was made, to substitute for the 25 C temperature of Hansen, the 19 degree C temperature of Applicant's admitted prior art, to increase transformation efficiency, with a reasonable expectation of success

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

15. Claims 22, 23, 29 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen, G. (US # 6,162,965) filed June 2, 1997, issued December 19, 2000, Bhojwani, SS et al (Developments in Crop Science, vol 5, pp 24-41, 1983), applied to claims 22,23 and 29, above, and further in view of Stomp (US 6,040,498,

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issued March 21, 2000). The teachings of Hansen and Bhojwani have been discussed *supra*.

The combination of Hansen and Bhojwani does not teach using an antibiotic at about 15 mg/L to about 75 mg/L. Stomp teaches culturing transformed tissue on an antibiotic (carbenicillin) to inhibit *Agrobacterium* growth, specifically at a range of 50 mg/L to 250 mg/L (column 17, lines 39-42). It would have been obvious to one of ordinary skill in the art, at the time of the invention, to utilize an antibiotic at the specified concentration to kill *Agrobacterium* after transformation. The choice of carbenicillin as taught by Stomp, or cefotaxime as taught by Hansen, is a matter of design choice, well within the means of one of ordinary skill in the art, without any surprising or unexpected results, depending on the selection marker utilized by the *Agrobacterium* transformation system.

Therefore, it would have been *prima facie* obvious to one of skill in the art to use the 50 mg/L carbenicillin concentration of Stomp to kill unwanted *Agrobacterium*, with reasonable expectation of success.

Claims 26 and 27 are free of the prior art.

Double Patenting

- The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 22-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-8, 12, 15, 17-21, 29, and 31 of copending Application No. 09/203,679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant case are broader and therefore, encompass the '679 claims. Thus, the species renders the genus obvious.

The claims of the instant application are drawn to a method for transforming corn comprising cocultivating immature embryos with *Agrobacterium*, capable of transferring a gene, on a medium comprising an antibiotic and a monosaccharide sugar. The claims of '679 are drawn to a method for transforming corn comprising cocultivating immature embryos with *Agrobacterium* capable of transferring a gene, applying heat shock during co-cultivation, culturing on a medium comprising an antibiotic. (Omitted limitations of these claims are identical). The "comprising" language in the method of the instant application encompasses the "applying a heat shock treatment" step of the '679 application. The instant case recites a medium comprising a "monosaccharide sugar", whereas '679 is silent on this limitation. However, it is well known in the art that monosaccharide sugars are stock components of plant tissue culture medium (Bhojwani, SS et al, *Developments in Crop Science*, vol 5, pp 24-41, 1983).

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Accordingly, the claims of the instant application are obvious in view of the claims of the '679 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

REMARKS

17. No claims are allowed.


18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer
Patent Examiner
Art Unit 1638
April 25, 2002




PHUONG T. BUI
PRIMARY EXAMINER